Docket No.: UAB-17404/22

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Fengxia Qi et al.

Application No.: 10/790,914 Confirmation No.: 1392

Filed: March 2, 2004 Art Unit: 1645

For: NOVEL LANTHIONINE ANTIBIOTIC COMPOSITIONS AND METHODS Examiner: V. L. Ford

APPELLANTS' REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 37 C.F.R. 41.41, this reply brief is filed within two months of the Examiner's Answer.

RESPONSE TO EXAMINER'S ARGUMENTS

A. Rejection of claims 9-28 under 35 USC §112, first paragraph: Claim enablement of making and using mutacin of SEQ ID NO. 2 commensurate with claims has been provided.

The claims that are the subject of this appeal encompass a well defined active antibacterial agent (SEQ ID No. 2) and the enablement rejection under appeal does not reach to the making and use of this mutacin protein as an antibacterial, rather the rejection focuses on the context (i.e. the target) against which the active agent operates. Appellant submits that this is the fundamental flaw in the appealed enablement rejection.

Examiner based the rejection of claims 9-28 for lack of enablement under 35 U.S.C. § 112, first paragraph concedes that the specification is enabling for treating some specific gram-positive bacterial infections. The Examiner's Answer maintains that the specification and declaration of Appeal Brief Appendix A that neither all gram-positive bacterial infection treatments per claim 9 have been enabled nor have the treatment of Staphylococcus, Enterococcus, and Streptococcus pneumoniae per claim 17 been enabled in spite of an additional showing as to S. pyogene, s. pneumoniae, multiple drug resistant Staphylococcus aureus, vancomycin resistant E. faecium and Bacillus anthracis. (Examiner's Answer, paragraph spanning pages 13-14)

Appellant has made of record evidence showing not only efficacy against broad classes of organisms but also the routine and indeed trivial nature of testing the claimed peptide sequence for antibacterial activity. Evidence the zone of exclusion testing of a substance in a Petri dish culture techniques has been made of record and is in fact common to introductory high school and college microbiology courses and a well recognized technique for modeling in vivo antibacterial activity. The discounting of in vitro data for antibiotic activity is an error since unlike other medications, an ideal antibiotic does not have any activity towards the subject harboring the infection by the bacteria. Here the Examiner cannot argue that the toxicity of the subject mutacin peptide toward a host is called into question as the specification makes clear that the mutacin of the claimed method is isolated form the mouth humans. Failure to afford proper weight to this data is reversible error.

As stated in MPEP 2164.02:

> "the examiner must weigh the evidence for and against correlation [between in vitro and in vivo] and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566,

34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications).

No such weight of evidence has occurred and is submitted to constitute reversible error.

As the record before the Board is devoid an Office challenge as to the truth or accuracy of the statements made of record, the Examiner is obligated to accept those statements for what they are: sworn statements of fact and/or belief. The record before the Board shows a large number of bacterial target genuses and species, from which enablement of the genus of "gram-positive" bacteria is supported per claim 9 and "Staphylococcus, Enterococcus, and Streptococcus pneumoniae" per claim 17 and the claims that depend thereform. Such a decision is requested from this Board.

B. Rejection of Claims 9 and 10 under 35 U.S.C. §102(b) as inherently anticipated by Loyola-Rodriguez et al. and separately by Ikeda et al.: "Comprising" as a claim transitory phrase does not excuse Examiner from finding claimed subject matter in a single prior art reference teaching.

The basis of anticipatory rejection under Loyala-Rodriguez et al. and separately Ikeda et al. has been inherent anticipation. The differences in peptide identity and molecular weight made of record are submitted provide a rationale for the reversal of these rejections. The statement found I The Examienr's anser on page 15 that the claims do recite a specific molecular weight for SEQ ID. No. 2 ignores the fact that the molecular weight of SEQ ID. No. 2 is definite based on a specific amino acid sequence being provided and the molecular weight of each amino acid being well known.

The fact that claim transitory phrase "comprising" is not exclusive of other substances is irrelevant to the establishment of an anticipatory rejection when the recited claim elements have not been found in the prior art. Anticipation requires at a minimum that all of the claim elements be found within a single prior art reference. No showing has been made by the Examiner that SEQ ID. No. 2 as detailed in the claims on appeal is actually present in any prior art reference as such the very basis of the anticipatory rejection is called into question.

Reversal of the outstanding anticipatory rejections is so requested.

The Director is hereby authorized to charge any fees, which may be required, or credit any overpayment, to Deposit Account Number 07-1180.

June 4, 2008

Respectfully submitted,
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